

ERYTHROMYCIN- erythromycin tablet, film coated
Zydus Lifesciences Limited

Erythromycin Tablets, USP

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

NDC 70771-1548-1 in bottle of 100 tablets

Erythromycin Tablets USP, 250 mg

Rx only

100 tablets



NDC 70771-1549-1 in bottle of 100 tablets

Erythromycin Tablets USP, 500 mg

Rx only

100 tablets

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NDC 70771-1549-1

Erythromycin
Tablets, USP

500 mg

100 Tablets
Rx only



Each film-coated tablet contains:
Erythromycin, USP.....500 mg

Usual adult dose: One tablet every twelve hours.
See accompanying prescribing information.

This package is child-resistant.

Store at 20°C to 25°C (68°F to 77°F); excursions
permitted to 15°C to 30°C (59°F to 86°F).
[See USP Controlled Room Temperature.]
Keep tightly closed.
Dispense in a USP tight container.

Do not accept if seal over bottle opening is
broken or missing.

Keep this and all drugs out of the
reach of children.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 03/23

ERYTHROMYCIN

erythromycin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1548
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ERYTHROMYCIN (UNII: 63937KV33D) (ERYTHROMYCIN - UNII:63937KV33D)	ERYTHROMYCIN	250 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST) (UNII: G4U024CQK6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 3OIQX730WE)	

POVIDONE K30 (UNII: U725QWY32X)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics

Color	PINK (light pink)	Score	no score
Shape	OVAL (oval)	Size	15mm
Flavor		Imprint Code	III
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1548-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2023	
2	NDC:70771-1548-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2023	
3	NDC:70771-1548-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212693	06/30/2023	

ERYTHROMYCIN

erythromycin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1549
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ERYTHROMYCIN (UNII: 63937KV33D) (ERYTHROMYCIN - UNII:63937KV33D)	ERYTHROMYCIN	500 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST) (UNII: G4U024CQK6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POVIDONE K30 (UNII: U725QWY32X)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics

Color	PINK (light pink)	Score	no score
Shape	OVAL (oval)	Size	19mm
Flavor		Imprint Code	1048
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1549-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2023	
2	NDC:70771-1549-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2023	
3	NDC:70771-1549-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212693	06/30/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1548, 70771-1549) , MANUFACTURE(70771-1548, 70771-1549)

Revised: 6/2023

Zydus Lifesciences Limited